

510(k) SUMMARY

MAR - 5 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

1. Submitter's Identifications:**Establishment:**

Alicia™ International Pty, Ltd.

84A Skyline Dr, Burleigh Heads, Gold Coast, Queensland, Australia 4220

Operations: Foreigner importer**Owner/Operator:**

Alicia™ International Pty, Ltd.

84A Skyline Dr, Burleigh Heads, Gold Coast, Queensland, Australia 4220

Date of Summary Preparation: April 2, 2007.

2. Name of the Device:

Alicia™ Menstrual Cup / 99ALXS, 100ALSM, 101ALMD, 102ALLG

3. Information of device classification.

Device	Cup, Menstrual
Regulation Description	Menstrual cup
Regulation Medical Specialty	Obstetrics/Gynecology
Review Panel	Obstetrics/Gynecology
Product Code	HHE
Regulation Number	884.5400
Device Class	II

4. Device Description:

The Alicia™ menstrual cup is a soft, small internally worn reusable silicone menstrual cup that holds (instead of absorbing) monthly menstrual flow. It may remain in the body for up to 12 hours. It holds an ounce of fluid. It is available four sizes:

- L size: 102ALLG; for larger built women that have had children.
- M size: 101ALMD; for women who have had vaginal childbirth or C-Section; and for women who are over 30 years old and never had childbirth.
- S size: 100ALSM; for women under 30 years old who have never had childbirth or C-Section.
- XS size: 99ALXS; for teenagers and very small framed women.

The cup remains entirely within the vagina and does not touch the cervix but the stem remains outside the body to ensure retrieval of the cup. See the user's manual for information about how to use and care for the Alicia™ menstrual cup.

The Alicia™ menstrual cup is manufactured from a soft silicone elastomer. The properties of the silicone are described in a master file at FDA. The master file provides data on all of the biocompatibility or toxicity testing required according to FDA's memorandum to guidance G95-1.

which MF?

5. Intended Use:

← Intended use for what?
The Alicia™ Menstrual Cup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation. The Alicia™ Menstrual Cup is placed low enough in the vagina to be retrieved readily and to prevent it's touching the cervix or interfering with menstrual flow through it.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

MoonCup® Menstrual Cup (K040335)

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ISO 10993-1 for biocompatibility as well as the specified testing standard of ISO 10993-5 and ISO 10993-10.

8. Conclusions

The Alicia™ Menstrual Cup / Model: 99ALXS, 100ALSM, 101ALMD and 102ALLG have the same intended use and technological characteristics as the cleared devices, Menstrual Cup (K040338). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore, the new device Alicia™ Menstrual Cup / Model: 99ALXS, 100ALSM, 101ALMD and 102ALLG is considered substantial equivalent to the chosen 510(k) cleared device MoonCup® Menstrual Cup (K040335).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

MAR - 5 2008

Alicia International PTY LTD
c/o Mr. Tom Stone
Official Correspondent
PO Box 1471
Oxenford 4210
QLD
AUSTRALIA

Re: K070965
Trade/Device Name: Alicia™ Menstrual Cup / Models 99ALXS, 100ALSM,
101ALMD, 102ALLG
Regulation Number: 21 CFR §884.5400
Regulation Name: Menstrual cup
Regulatory Class: II
Product Code: HHE
Dated: February 21, 2008
Received: February 21, 2008

Dear Mr. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: Alicia™ Menstrual Cup / Models 99ALXS, 100ALSM, 101ALMD, 102ALLG

Indications For Use:

The Alicia™ Menstrual Cup / Models 99ALXS, 100ALSM, 101ALMD, 102ALLG is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

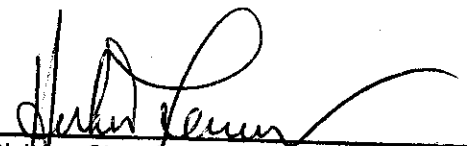
Prescription Use _____
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use √
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070965

Page 1 of 1